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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/667,380	09/22/2000	Gregory Donoho	LEX-0042-USA	9804

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EXAMINER

MITRA, RITA

ART UNIT	PAPER NUMBER
1653	✓

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

	Application No.	Applicant(s)
	09/667,380	GREGORY DONOHO
	Examiner	Art Unit
	Rita Mitra	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 April 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) Interview Summary (PTO-413) Paper No(s). _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-3 are currently pending and are under examination.

Oath or declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing or post office address of inventor Glen Friedrich. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Objection to the Specification

The disclosure is objected to for the following informalities:

The abstract of the disclosure is objected to because the abstract is not descriptive.

Appropriate correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 encompasses the subject matter that is not defined in the specification. The claim is directed to an isolated nucleic acid molecule comprising at least 24 contiguous bases of nucleotide sequence first disclosed in the NHP gene described in SEQ ID NO: 1. It is clear from the specification that Applicants were in possession of SEQ ID NO: 1 at the time the invention was made. However, the specification, have given no concise definition of the novel human protein (NHP). The specification indicates (see page 2-7), that the novel human proteins (NHP), share structural similarity with animal trypsin inhibitor proteins. Additionally the invention contemplates any nucleotide sequence encoding a contiguous NHP open reading frame (ORF), however specification fails to provide any description of the fragments or the contiguous bases within the polynucleotide that retain the activity of the full length NHP which has an activity of the trypsin inhibitor protein. The claims are directed to an isolated nucleic acid molecule comprising nucleic acid sequence set forth in SEQ ID NO: 1 and a fragment thereof. However, the specification provides only a generic description of how a variety of fragments/variants can be generated (page 4-7), no specific guidance is provided on the generation of the fragments or variants that demonstrate the biological activity of the peptide sequence of SEQ ID NO: 2. Therefore, there is lack of written descriptions as to what are those nucleic acid molecules comprising 24 contiguous bases of SEQ ID NO: 1 that constitutes a polynucleotide of NHP gene as claimed.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Regarding claim 1, the specification does not enable the skilled artisan to use the claimed polynucleotide because the specification fails to provide a written description of a polynucleotide that has at least 24 contiguous bases of the corresponding polynucleotide sequence that is disclosed in NHP gene.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because of the use of the term “NHP.” An acronym/abbreviation should be preceded by the full spelled out word. Claim 1 is also indefinite because of the use of the phrase “first disclosed.” What is the first? First to what?

Claim 2 is indefinite because of the use of the word “stringent.” It is not clear whether it is high, moderate or low stringent condition. Recitation of the stringent hybridization condition in the claim will overcome this rejection.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 is rejected under 35 U.S.C. 102(a) as anticipated by Kaplan et al. (Am. J. Physiol. Vol 276 (6), L1027-L1036, June, 1999, IDS Ref. XP002169299). Kaplan et al. teach a novel developmentally regulated gene in lung mesenchyme having homology to a tumor-derived trypsin inhibitor LGL1 isolated from fibroblast cDNA library. Kaplan et al. teach a cDNA comprising 32 contiguous bases (position 220-251) of nucleotide sequence of SEQ ID NO: 1 (see alignment result Database: GenEmbl, Accession NO: AF109674). Kaplan’s nucleic acid

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sequence of LGL1 is considered for a fragment of the nucleic acid sequence set forth in SEQ ID NO: 1 having at least 24 contiguous bases thus anticipating claim 1 of instant application.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



KAREN COCHRANE, CARPENTER, PH.D.
PRIMARY EXAMINER



Rita Mitra, Ph.D.

September 22, 2002